



UNITED STATES DEPARTMENT OF COMMERCE
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08/178,463	01/06/94	WILSON	W 20264034US1

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GOLDBERG J	
ART UNIT	PAPER NUMBER
1205	22

DATE MAILED:

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Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run _____ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

- ☐ Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
 - b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
 - c. ☐ They raise the issue of new matter. (See Note).
 - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
 - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: none

Claims objected to: none

Claims rejected: 15

However;

- ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because Chabwa's declaration is based on "my opinion and belief" and not facts

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

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PRIMARY EXAMINER
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Art Unit 1205

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1 and 3-11 are rejected under 35 U.S.C. § 103 as being unpatentable over the Rowinsky et al., Holmes et al. and Gilman et al. reference of record. The Rowinsky et al. teaches the applicant' taxol for 24 hours of 200-250mg/m² by i.v. infusion. ~~Applicants are employing taxol for 96 hours at the~~ Holmes et al. reference teaches taxol for treating breast cancer at 250mg/m² for 24 hours infusion every 21 days. The Gilman et al. reference teaches 30mg/m² per day for 5 days or 210mg - 250mg

Art Unit 1205

given every 3 weeks. Applicants are employing taxol for 96 hours at 140mg/m² by i.v. infusion. The difference is in the number of hours and the amount being employed. In view of this, one skilled in the art could be motivated to employ the i.v. infusion of the prior art for a long period of time in the absence of a side-by-side comparison.

Claims 1 and 3-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3-11 are improperly drawn to two different steps. The step of preparing an infusion solution and the step of infusion. The terms "at least 24 hours" in claims 1, 3 and 4 and "at least 96 hours" in claims 6-9 is indefinite in failing to recite an upper limit.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or 305-3592.

Any inquiry concerning this communication should be directed to Examiner Goldberg at telephone number (703) 308-1235.

GOLDBERG:jd
April 08, 1994



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